



February 20, 2007

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Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Attention: **CMS-2238-P**

Re: Proposed Rule: Medicaid Program; Prescription Drugs

Dear Ms. Norwalk:

The American Public Human Services Association (APHSA) and its affiliate, the National Association of State Medicaid Directors (NASMD), respectfully submits this comment letter on the Medicaid prescription drug benefit. APHSA and NASMD are commenting on the proposed rule published in the December 22, 2006 Federal Register (71 FR 77174) for the Centers for Medicare and Medicaid Services (CMS). Please be assured that the state Medicaid agencies are fully committed to implementing the prescription drug related provisions of the Deficit Reduction Act of 2005 (DRA) and to their respective initiatives that seek to improve the efficiency of the Medicaid pharmacy benefit.

APHSA and NASMD believe that the DRA included important provisions that could facilitate increased transparency in prescription drug pricing in the Medicaid program and provide states with the tools they need to improve the accuracy of their reimbursement methodologies. States also recognize that these are essential steps in providing quality, affordable care to Medicaid consumers.

Medicaid's fundamental federal-state partnership necessarily means that states have a vested interest in ensuring the policy on drugs ensures ease of implementation. Further, states have an interest in assuring that the Congressional intent with respect to the DRA provisions can be implemented. As CMS continues to evaluate the best course of action to achieve these goals, we are submitting comments in the following areas:

- Ensuring the accuracy of average manufacture price (AMP) data for use in validating states' reimbursement methodologies and establishing AMP-based federal upper limits (FULs);
- Providing states with the flexibility to respond to market forces in a timely fashion; and
- Minimizing procedural challenges and recommending steps to improve the efficiency of collection of rebates on physician administered drugs.

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Definitions – Section 447.502

Definition of Dispensing Fee

The proposed dispensing fee definition infers a specific methodology – that is a cost-based calculation not reflective of economies and competition in the marketplace. This is inconsistent with the intent of Congress and the administration to provide states' with the flexibility to set their own dispensing fee levels. In addition, it may result in Medicaid rates that are not representative of a marketplace in which other insurers consistently pay lower rates for ingredient costs and dispensing fees together than most Medicaid programs.

States also have noted that the proposed definition allows payment of a dispensing fee each time a drug is dispensed, regardless of whether such dispensing is consistent with economical practices. States have identified situations where some pharmacies, sometimes colluding with prescribers, fraudulently split maintenance drug prescriptions to obtain additional dispensing fee payments. States request that CMS clarify the proposed definition so that it does not preclude states from preventing such behaviors.

Determination of AMP – Section 447.508

In its proposed rule CMS requested input on its definition of AMP. With regard to mail order pharmacies, states note that mail order pharmacies are able to capitalize on their economies of scale by purchasing in bulk and dispensing in large quantities. Additionally, mail order and other large scale purchasers have access to discounts that are not available to rural or sole proprietorship pharmacies. Based on this disparity, CMS should consider excluding mail order pharmacies in the AMP calculation.

CMS also requested comments on the new AMP calculation for setting FULs on generic drugs and whether there could be possible impacts on utilization and reimbursement for brand name drugs under Medicaid. States have conducted initial evaluations of the AMP data and will need additional time to conduct more comprehensive assessments and fully evaluate the new AMP-based FULs. Further, states believe it may be premature to evaluate the changes and impact of AMP pricing in the marketplace that may occur over time.

At this time, states note that there could be a challenge in achieving the most accurate reimbursement while not indirectly creating a disincentive to dispense generic prescription drugs. Some states have raised concerns that the proposed AMP-based reimbursement could discourage generic dispensing and have the unintended effect of increasing brand utilization and Medicaid costs. That is, if the aggregate impact of the AMP-based FULs results in a shift to brand name drugs and/or increase in dispensing fees, this could cause inefficiencies in the Medicaid prescription drug benefit. In addition, states recognize that provisions of the proposed rule may directly or indirectly impact their provider network, particularly in communities with small providers and/or those dependent on one provider.

For these reasons, states urge CMS to examine the range of factors – in addition to the ingredient costs – impacting states' reimbursement methodologies and preserve states flexibility to maintain a reasonable, market-based threshold for reimbursement. States ask that CMS consider the variations in prices and availability across states. We wish to offer for CMS' consideration the

possibility of creating an appeals process to allow pharmacies, drug wholesalers, and states to report situations whereby prescription drugs are not available or not available at the prices listed under the AMP-based FUL. For example, rural pharmacies may not have access to the same pricing available to larger markets or mail order pharmacies. Confirmed reports could result in CMS raising or suspending a FUL.

States also offer for your consideration that the appropriate definition of fair market value can only be truly determined by measuring the prices wholesalers charge all pharmacies in the aggregate on a real-time basis. In general, the wholesaler effect needs to be considered an essential component of this equation to accurately and equitably determine “fair market value.”

Requirements for Manufacturers – Section 447.510

States believe that the DRA and this proposed rule begin to elaborate on the important steps that will help to increase access to and transparency of AMP data and a more appropriate reimbursement system, including by defining AMP in statute and regulation. However, states have identified several challenges and concerns with the proposed rule related to AMP.

AMP Data

States strongly encourage CMS to ensure that the AMP data is of a level of quality that will permit states to validate their current reimbursement methodology and improve the efficiency of the Medicaid pharmacy benefit. At a minimum, standard AMP data should reflect only those products currently available and be based on a specified supply time period, specifically:

- 1) CMS began providing states with sample or “non-standard” AMP data in July of 2006, and, based on this information, most states have conducted preliminary analysis of the AMP data. States have reported that there are a significant number of terminated products or products that were not available in every state that were included in the manufacturers’ lists. The result is that states are presented with new challenges and questions as to why manufacturers would be reporting such data, even if this were a “sample” AMP file.
- 2) Some states have reported that there is significant fluctuation in AMP and that this inconsistency could result in inaccurate estimates of the acquisition costs that providers pay. This also could result in fluctuating FULs, thereby making it difficult for states to make timely and reasonable adjustments to their reimbursement methodologies to reflect such fluctuations. At the onset of implementation of the DRA provisions, states believe that it would be appropriate to provide additional time to allow states to monitor the fluctuations of the complete AMP data before they could make adjustments in reimbursement.
- 3) We encourage CMS to provide additional guidance on FUL pricing for prescription drugs that is not based on a different supply schedule, that is, by the actual package size of the drug. A FUL set on a weighted AMP by package price may not cover the actual acquisition costs of pharmacies purchasing smaller package sizes – while other pharmacies purchasing larger package sizes would be over paid.

Accountability for Accurate Data

We respectfully request that CMS assist in verifying the accuracy of the data by implementing accountability measures for manufacturers. States understand from the CMS call held on January 4, 2007, that the agency believes that the transparency of AMP information should help to reduce the erroneous data problem. However, states remain concerned by the lack of controls and accountability measures for manufacturers. In addition, the historical experience of states indicates that existing CMS processes have been insufficient in monitoring and managing the prescription drug files. The lack of updated data can reasonably be expected to result in inappropriate FUL calculations and impose an unforeseen burden on states to identify and subsequently report any inaccuracies to CMS.

As a result, states urge CMS to implement systems checks and measures to hold manufacturers accountable for the quality of data they provide, including reporting or not reporting accurate data. States request that in developing this system of checks and accountability measures, CMS include representation from state Medicaid agencies in addition to CMS representatives.

Implementation Timeline

States are concerned that the final regulation may not be published until July 1, 2007 and that many questions essential to implementation of the proposed rule will remain unanswered until this time. We understand that this is the date specified in the DRA. However, we urge CMS to consider and account for the steps states' will need to take in order to operationalize the final rule and meet this deadline.

States are unlikely to have the processes and systems in place for a number of reasons, including:

- 1) States must wait for CMS to finalize the provisions of this rule before they can develop the systems and processes to implement it, otherwise, states will have to undertake a second implementation initiative to reflect the changes and additional information CMS is expected to provide in the final rule.
- 2) Although states received AMP data in 2006, this was sample data, so they will have had insufficient time to evaluate the monthly fluctuations in AMP and any impacts on various facets of their Medicaid program. As noted above, the sample data was inaccurate and insufficient to make firm policy decisions. Any changes that states will need to make to their state Medicaid plan or dispensing fees are likely to require state legislation and/or submission of a state plan amendment and this will take considerable time.
- 3) The implementation timeframe is short and some states are unlikely to have the staff and funding resources to meet the deadline.

Transfer of AMP Files

Finally, with regard to AMP, the proposed rule states that CMS will distribute the monthly AMP file to states. States are concerned that the monthly file that CMS intends to send will contain only the drug name. In turn, states will have to translate the drug descriptions in the file that will enable them to easily analyze the impacts of the FUL with their processed claims. In addition, providing the file to states in such a fashion may lead to misinterpretations and lack of identification of applicable products with their National Drug Codes (NDCs) that are necessary to

process claims. In essence, this will require many states to invest new resources to manage this information.

States believe CMS can and should assist in making this process more efficient. We believe there would be a significant strain on states' resources if they were required to manage all of the new AMP data, including pricing updates, manually without some assistance. Therefore states request that CMS consider alternative mechanisms to facilitate states' utilization of workable data in a timely fashion. Specifically, a mechanism is needed that applies the rate to the new NDC that meet those criteria listed in the proposed rule. One possibility is to provide the file on at least a monthly basis to the nationally recognized pricing compendia that, in turn, could provide descriptive drug information, unique identifiers and pricing data, including updated NDC codes, within the file that would be distributed to states.

New FUL Calculation and Impact on Preferred Drug Lists

States also urge CMS to consider the adverse impact that the new AMP-based FUL could have on state prescription drug lists (PDLs) that have otherwise been effective in helping to appropriately contain costs in the Medicaid prescription drug benefit. For example, every month states could be required to consider the new AMP-based FUL for their respective PDLs. States have noted that in addition to procedural difficulties with this process, there may be challenges and unintended consequences on the level of savings expected to accrue from the new FUL if the net cost to the federal government and a particular state is less than the costs of generic. Specifically, this could compromise supplemental rebate agreements that states have in place in situations where the federal rebate and supplemental rebate together produce greater savings than the new FUL.

Access to Data for Territories

APHSA and NASMD also respectfully request that CMS provide the U.S. territories with access to the new AMP data so they may leverage the information in their calculations for reimbursement on brand-name and generic drugs, as well as on rebates negotiations with the drug companies. Access to the proposed new AMP data will provide a benchmark in the rebate negotiation process, maximizing the utilization of available Medicaid funds.

Drugs: Aggregate Upper Limits of Payment – Section 447.512

The proposed rule includes an exception to allow providers to indicate when a specific brand drug is medically necessary for a particular recipient. However, CMS has indicated that this exception is permitted only in instances when the physician “certifies in his or her own handwriting” that the drug is necessary. States request that CMS reconsider this requirement as it is contradictory to state and federal efforts to transition to e-prescribing and other health information technology innovations.

Upper Limits for Multiple Source Drugs – Section 447.514

In the proposed rule, CMS notes that Congress did not intend that AMP should be restructured to collect it by 11-digit National Drug Codes (NDCs) and that this would create a new burden for manufacturers. We respectfully disagree with CMS' decision not to restructure the information collection method. Rather, the 11-digit NDC methodology will more accurately reflect the prices

paid by the majority of rural and sole proprietorship pharmacies. Specifically, states note that in some areas there is a lack of availability of all package sizes. This is particularly the case with rural or sole proprietorship pharmacies. Thus, the 9-digit NDC favors large scale purchasers and mail order pharmacies who capitalize on economies of scale by purchasing pharmaceuticals in the largest package size or those available in bulk where this methodology is not financially feasible or available to our rural pharmacies. States also recommend that AMP-based FUL pricing should be calculated on standardized package sizes.

FFP: Conditions Relating to Physician Administered Drugs – Section 447.520

The DRA called for a number of changes to improve the efficiency of billing methodologies for physician administered drugs. States are prepared to work with CMS to develop the appropriate measures and guidance that will be needed to ensure these provisions are implemented effectively.

Provider education

States are concerned that the proposed rule does not take into account the extensive education and systems updates that will be required to ensure that providers can comply with the new physician administered drug billing methodologies. A “standardized rebatable labeler list” would help to avert states having to deny claims several months later. States expect the change in the billing system and practices to be an especially acute problem in situations of small provider groups or among providers that utilize separate contractors for their billing systems.

As such, states respectfully request that CMS inform providers of the Healthcare Common Procedure Coding System (HCPCS) codes will require a National Drug Code (NDC) that they can bill the state. As stated above, without this information, providers may not know who is and is not a rebating labeler.

In addition, we believe that it would be an onerous requirement to mandate states – without any assistance from CMS – to work with providers to ensure that these codes are collected for rebatable drugs. States believe that since this is a national issue impacting all states and providers in the same way, it is reasonable to request that CMS develop standardized literature to educate providers rather than requiring each Medicaid agency to develop its own materials.

States also believe that CMS has significantly underestimated the burden of this provision on states if it is implemented as proposed. At a minimum, CMS should revise its burden estimate to account for the extensive education and outreach that states will ultimately be required to undertake.

Aligning Medicare and Medicaid rules

States also request that CMS provide clarification and guidance on the rule’s impact and interaction with Medicare. There are a significant number of providers that will be impacted because of Medicaid’s role in providing coverage for individuals dually eligible for Medicare and Medicaid. States are concerned that the proposed rule does not address the impact on Medicare carriers and, in turn, this will create obstacles in Medicaid agencies’ ability to efficiently comply with these provisions. In fact, based on previous experience working with Medicare providers, states believe that Medicare carriers are not prepared to provide detailed NDC information that is

necessary to ensure that Medicaid can obtain the rebate, when applicable. Without this information, there could be a significant number of denied claims that may not be able to be resolved. In turn, beneficiaries could receive bills for denied claims or be refused treatment.

States urge CMS to use its authority to ensure that the Medicare and Medicaid rules align so that state Medicaid agencies can comply in a timely, efficient manner. That is, CMS should require Medicare to do a “crosswalk” and address Medicare’s responsibility in providing rebate information for certain prescription drugs provided to a dually eligible beneficiary.

Impact on DMERC

Many states currently do not receive an NDC from a DMERC. However, states believe that the standardization of physician administered drugs necessarily should impact DMERCs and that there may be a multitude of requirements for DMERCs. As such, states also request that CMS provide clarification and guidance on the role and responsibilities of DMERCs with regard to the provisions of the proposed rule.

NDC requirement for HCPCS drugs

In addition, states note that there will be operational challenges associated with the NDC requirements for HCPCS prescription drugs. There are two paper forms, the CMS 1500 and the UB04 that are in use. The electronic 837 format for both the CMS 1500 and UB04 can accommodate the NDC, including the NDC quantity. However, the paper version of the UB04 does not have a space for this information. CMS has indicated that each state should develop its own unique form.

States urge CMS to reconsider this issue, particularly given the limited timeframe available to adopt a new form. Due to the administrative procedures and existing demands on state staff, states face great challenges in meeting this requirement. Instead, states respectfully request that CMS develop a standard UB04 form that provides for a way to indicate the NDC. This will guarantee uniformity across states and ensure that states are not subject to lose any rebates or revenues.

Hardship waiver

CMS in the proposed rule and in its verbal communication with states indicated that the agency does not expect that states will need a hardship waiver to meet these requirements. For the reasons stated above and other factors impacting state Medicaid programs, such as the concurrent implementation of the National Provider Identification number (NPI) and ongoing systems upgrades that cannot accommodate the change in the specified timeframe, states respectfully request that CMS be amenable to the possibility that a hardship waiver may be needed in some states and be prepared with a hardship waiver process.

Retail Price Survey

Although this proposed rule does not specifically address Section 6001(e) of the DRA which provided for a survey of retail prices and state performance rankings, states wish to offer comments that we believe impact this proposed rule and CMS’ related work on the retail price survey. As it finalizes this process, states request that CMS consider various factors and unique state situations that will impact this information. Specifically, pharmacies are required to bill

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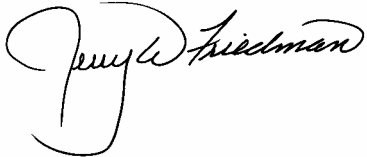
Medicaid their usual and customary price that is supposed to reflect what the pharmacy charges a "regular" customer. However, although states are diligent in ensuring that pharmacies are compliant with Medicaid policies, due to misunderstandings associated with this requirement, there may be some pharmacies that increase the rate they charge to Medicaid programs because they do not think they have to charge the same to both types of customers. This could skew the data used in the retail price survey. In addition, in the state reimbursement price ranking, the state supplemental rebates are excluded in the best price determination. However, for gross payments made to pharmacies this does not reflect the true price a state Medicaid agency may be paying. In turn this will skew the ranking and could result in over reporting. As such, states strongly encourage CMS to make note in its report of these and any other factors that clarify the results.

Regulatory Impact

States respectfully request that CMS reconsider or clarify the level of administrative costs associated with this regulation. Specifically, CMS should provide estimates of the federal and state administrative costs. This estimate should reflect the fact that AMP-based FUL pricing is not currently in effect. Although the rule has not yet been finalized, states already have invested significant time and resources assessing the impact of AMP and the proposed rule.

We would be pleased to meet with you at any time or provide any additional information that may helpful to you on these matters. Thank you for considering our comments. If you have any questions, please do not hesitate to contact me or Martha Roherty at (202) 682-0100, ext. 299.

Sincerely,



Jerry W. Friedman
Executive Director



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